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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,043	KOLA ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *110-113 and 159-167* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *110 and 113* is/are allowed.

6)☒ Claim(s) *111,112 and 159-167* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 February 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 11/11/9/04. The amendment has been entered. Claims 110-113 and 159-163 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. For example, see page 16, line 22 of the specification and page 58, line 16. All embedded hyperlinks in the specification must be deleted.

Claim Objections, minor informalities

Claim 161 is objected to because of the following informalities: it appears that there is a typographical error in the claim. Specifically, the claim recites the term "complimentary" which is considered to be a misspelling of "complementary" which appears in claims 159, 163, 165 and 167. Amending the misspelled word to read "complementary" would obviate this objection.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 160-167 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 160-163 recite "at least 98% similar" and claims and Claims 164-167 recite "at least 95% similarity". With respect to the terms "similar" and "similarity", it is noted that the specification states, "Where there is non-identity at the amino acid level, 'similarity' includes amino acids that are nevertheless related to each other at the structural, functional or biochemical and/or conformational levels" (See p. 16, lines 12-14). Therefore, the specification defines similarity/similar as "nevertheless related" at the structural, functional or biochemical and/or conformational levels. The phrase "nevertheless related" is a relative term and does not particularly define how the amino acids are related. That is, it is not clear which structural, functional or biochemical and/or conformational elements must be the same and which may be different between "similar" amino acids or amino acid sequences. It is not apparent from the specification which amino acids or amino acid sequences would be related at the structural/functional/biochemical/conformational level and which ones would not be related. As such the metes and bounds of the claims cannot be determined and the claims are indefinite.

Additionally, claims 164-167 recite the phrase "an amino acid sequence having at least 95% similarity to the amino acid sequence set forth in SEQ ID NO: 2, wherein said amino acid

sequence comprises an ETS domain" (Emphasis added). The phrase it is unclear which amino acid sequence "said amino acid sequence" is intended to refer to. As such, it is unclear which amino acid sequence (i.e. the sequence having similarity to SEQ ID NO: 2 or the amino acid sequence of SEQ ID NO: 2) must have an ETS domain.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 160-167 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Claims 160-163 encompass an isolated nucleic acid molecule comprising a nucleotide sequence encoding an amino acid sequence having an ETS domain wherein said ETS domain is at least **98% similar** to the sequence set forth in residues 165-243 of SEQ ID NO: 2, as well as a nucleic acid sequence complementary, as well. Claims 164-167 encompass an isolated nucleic

acid molecule encoding a sequence having at least 95% similarity to SEQ ID NO: 2. It is noted that the specification has been thoroughly searched for a disclosure of the amino acid sequences **98% similar** to the sequence set forth in residues 165-243 of SEQ ID NO: 2, as well as a sequence having at least **95% similarity** to SEQ ID NO: 2. The closest disclosure found is the disclosure that the mouse ELF5 ETS domain is **98% identical** to the ETS domain of human ELF5 (e.g., see Figure 2b), and the disclosure that the human and mouse ELF5 amino acid sequences are highly conserved with "approximately 95% identity" (See p. 52 lines 4-5). It is noted that the instant claims encompass a genus of nucleic acid sequences wherein the sequence encodes a polypeptide having an ETS domain that is **98% similar** to the human ELF5 ETS and a genus of amino acid sequences wherein the sequences have at least **95% similarity** to SEQ ID NO: 2. It is noted that the specification defines "similarity" (with respect to amino acid sequences) as, "Where there is non-identify at the amino acid level, "similarity" includes amino acids that are nevertheless related to each other at the structural, functional, biochemical and/or conformational levels." (See p. 16, lines 12-14). Therefore, it is clear that "98% similar" and "95% similarity" encompass molecules that are less than "98% identical" and "95% identical". As such, the claims encompass limitations that are not disclosed in the specification because there is no disclosure of any amino acid sequences that are 98% similar to the indicated ETS domain other than the one specific mouse ELF5 ETS domain which is 98% identical nor is there a disclosure of any sequence which have at least 95% similarity to SEQ ID NO: 2 other than mouse ELF5 and human ELF5.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, the instant claims are also rejected under 35 U.S.C. 112, first paragraph, as

containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP §2163.06 notes:

If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

MPEP §2163.06 further notes:

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure. (Emphasis added).

Claims 111, 112 and 159-167 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Thus, an applicant complies with the written-description requirement by describing the invention, with all its claimed limitations, and by using such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical, structure/function correlation, methods of making the claimed product, and any combination thereof.

Claim 111 is drawn to an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1 or which hybridizes to SEQ ID NO: 1 under medium stringency conditions. This claim encompasses any nucleotide sequence which hybridizes to SEQ ID NO: 1 under medium stringency conditions, including sequences wherein only a portion of the sequence hybridize to SEQ ID NO: 1 (e.g., a probe that has limited sequence homology to SEQ ID NO:1). Claim 112 is drawn to the nucleic acid sequence of claim 111 which further encodes the amino acid sequence set forth in SEQ ID NO: 2; therefore, the claim encompasses all of the limitation of claim 111 and includes nucleic acids wherein only a small portion of the sequence hybridizes to SEQ ID NO:1 and the sequence further comprises sequence which encodes SEQ ID NO: 2.

Claims 111 and 112 encompasses a genus of molecules that is indeterminate in size, but could possibly encompass millions of different species molecules considering every possible

polynucleotide which could comprise a sequence that hybridizes to SEQ ID NO:1, as indicated in the claim. Looking to the specification, it appears that the specification has only disclosed SEQ ID NO: 1, 3, 5, 6 and 8-15 (SEQ ID NO: 1-3 encode an ELF5 protein while SEQ ID NO: 8-15 are probes). Therefore, the specification has only disclosed 12 specific species encompassed by the claim. The specification does not appear to disclose any variant sequences, such as sequences that are not identical to SEQ ID NO:1, but which merely comprise nucleotides identical to sequences within SEQ ID NO:1. Nor is there any guidance provided which would indicate which variant sequences encompassed by the claim would hybridize to SEQ ID NO:1 under medium stringency conditions. Therefore, the specification has not adequately described a "representative number" of species encompassed by the claims.

Claim 159 is drawn to an isolated nucleic acid molecule comprising a nucleotide sequence complementary to a nucleotide sequence encoding SEQ ID NO: 2. Similarly, this claim encompasses any nucleotide sequence which hybridizes to a nucleotide sequence encoding SEQ ID NO: 2 including molecules that comprise sequences which do not hybridize to a nucleotide sequence encoding SEQ ID NO: 2 (e.g., a probe that has limited sequence homology to a nucleic acid encoding SEQ ID NO:2).

Claim 115 encompasses a genus of molecules that is indeterminate in size, but could possibly encompass millions of different species molecules considering every possible polynucleotide which could comprise a sequence complementary to a nucleic acid encoding the amino acid sequence set forth in SEQ ID NO:2. Looking to the specification, it appears that the specification has only disclosed 8 probes (SEQ ID NO: 8-15) which are complementary to a nucleic acid sequence encoding SEQ ID NO:2. Therefore, the specification has disclosed 8

specific species encompassed by the claim. The specification does not appear to disclose any variant sequences which merely comprise a sequence complementary a nucleic acid encoding SEQ ID NO: 2. Therefore, the specification has not adequately described a "representative number" of species encompassed by the claims.

Claims 160-163 are drawn to an isolated nucleic acid molecule (and complement) comprising a nucleotide sequence encoding an amino sequence having an ETS domain that is at least 98% similar to residues 165-243 of SEQ ID NO:2. These claims encompass any polypeptides that comprises a domain that is at least 98% similar to residues 165-243 of SEQ ID NO:2, including polypeptides that could have different biochemical structures and functions (e.g., some could be transcriptions activators while others could be transcription inhibitors).

The instant claims encompass a genus of molecules that is indeterminate in size, but could possibly encompass millions of different species molecules considering every possible polynucleotide which could encode a sequence having a domain that is at least 98% similar to residues 165-243 of SEQ ID NO:2. Looking to the specification, it appears that the specification has only disclosed 2 specific sequences which are disclosed as being 98% identical, the sequence encoding human ELF5 sequence (SEQ ID NO:1) and sequence encoding the mouse ELF5 sequence (SEQ ID NO:3) (see Figure 2B). As indicated above, the claims encompass molecules that encode proteins having a domain 98% similar to residues 165-243 of SEQ ID NO:2, including polypeptides which could have completely different functions, such as transcription activators as well as transcription inhibitors. The specification does disclose the sequence of ETS domains of several different proteins, as well as the ETS consensus sequence (See Figure 2b). However, of the sequences disclosed, only 2 are at least 98% identical to residues 165-243

of SEQ ID NO: 2 and they are the ETS domain of SEQ ID NO: 2 itself (human ELF5) and the ETS domain of SEQ ID NO:4 (mouse ELF5). Considering the definition of "similar" provided by the specification (see p. 16) it is unclear which sequences other than human ELF5 and mouse ELF5 also comprise a domain that is at least 98% similar to residues 165-243 of SEQ ID NO:2. Therefore, the specification has not adequately described a "representative number" of species encompassed by the claims.

Claims 164-167 are drawn to an isolated nucleic acid molecule (and complement) comprising a nucleotide sequence encoding an amino sequence having least 95% similarity to SEQ ID NO:2. These claims encompass any polypeptides that comprises a domain that is at least 98% similar to residues 165-243 of SEQ ID NO:2

The instant claims encompass a genus of molecules that is indeterminate in size, but could possibly encompass millions of different species molecules considering every possible polynucleotide which could encode a sequence having at least 95% similarity SEQ ID NO:2. Looking to the specification, it appears that the specification has only disclosed 2 specific sequences which are disclosed as encoding a sequence having at least 95% similarity to SEQ ID NO:2: the sequence encoding human ELF5 sequence (SEQ ID NO:1) and sequence encoding the mouse ELF5 sequence (SEQ ID NO:3). As indicated above, the claims encompass molecules that encode proteins having at least 95% similarity SEQ ID NO:2, including nucleic acids encoding polypeptides which could have completely different functions, such as transcription activators as well as transcription inhibitors. Considering the definition of "similarity" provided by the specification (see p. 16) it is unclear which sequences other than sequence encoding

human ELF5 and mouse ELF5 would constitute a sequence encoding a polypeptide having at least 95% similarity SEQ ID NO:2. Therefore, the specification has not adequately described a "representative number" of species encompassed by the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 160 and 161 are rejected under 35 U.S.C. 102(b) as being anticipated by Tymms et al. (Oncogene 1997; Vol. 15, pages 2449-2462).

The instant claims are drawn to an isolated nucleic acid molecule (and complement) comprising a nucleotide sequence encoding an amino sequence having an ETS domain that is at least 98% similar to residues 165-243 of SEQ ID NO:2. As indicated above, the claims are very broad and encompass any isolated nucleic acid that encodes a polypeptide having an ETS domain that is at least 98% similar to residues 165-243 of SEQ ID NO:2. It is noted that, with respect to the terms "similar" the specification states, "Where there is non-identity at the amino acid level, 'similarity' includes amino acids that are nevertheless related to each other at the structural, functional or biochemical and/or conformational levels" (See p. 16, lines 12-14).

Therefore, the specification defines similarity/similar as "nevertheless related" at the structural, functional or biochemical and/or conformational levels. The phrase "nevertheless related" is a relative term and does not particularly define how the amino acids are related. That is, it is not clear which structural, functional or biochemical and/or conformational elements must be the same and which may be different between "similar" amino acids or amino acid sequences. It is not apparent from the specification which amino acids or amino acid sequences would be related at the structural/functional/biochemical/conformational level and which ones would not be related. However, given the broadest reasonable interpretation, the claims encompass a sequence encoding a polypeptide that has a functional ETS domain. That is, given the broad definition of "similar", any sequence which encodes a polypeptide that has a functional ETS domain is encompassed by the claims, wherein a "functional" ETS domain is a domain that specifically binds to the ETS binding sequence.

Tymms teaches two different nucleic acids which polypeptides having functional ETS domains. Specifically Tymms teaches a nucleic acid sequence encoding human ELF3 and a sequence encoding mouse ELF3 (e.g., see abstract; Figure 1 on page 2450, Figure 2 bottom of p. 2452 and 2453, etc.). Furthermore, Tymms teaches that sequences encode polypeptides that specifically bind to the consensus ETS binding domain in an electrophoretic mobility shift assay (EMSA) (see Figure 7, page 2457). Therefore, Tymms teaches two different sequences which meet the limitations of the instant claims.

Claims 111 and 159 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,858,731 (Sorge et al.).

The instant claims are drawn to an isolated nucleic acid molecule comprising the nucleotide sequence as set forth in SEQ ID NO:1 or which hybridizes to SEQ ID NO:1 under medium stringency conditions (claim 111; emphasis added) as well as an isolated nucleic acid molecule comprising a nucleotide sequence complementary to a nucleotide sequence encoding the amino acid sequences as set forth in SEQ ID NO:2 (Claim 159). It is noted that claim 111 is interpreted as being drawn to an isolated nucleic acid molecule comprising the nucleotide sequence as set forth in SEQ ID NO:1 or an isolated nucleic acid molecule which hybridizes to SEQ ID NO:1 under medium stringency conditions (based on the presence of the word "or" in the claim). Furthermore, it is noted that the amino acid sequence set forth in SEQ ID NO:2 is encoded by the sequence of SEQ ID NO:1. As such, any nucleic acid which would hybridize to SEQ ID NO:1 under medium stringency conditions would, by necessity, also be a nucleic acid molecule comprising a nucleotide sequence complementary to a nucleotide sequence encoding the amino acid sequences as set forth in SEQ ID NO:2.

Sorge teaches an isolated oligonucleotide consisting of the sequence 5'-TTTTCTAC-3'. Specifically, see the 8mer oligonucleotide disclosed as Oligo No. 8A in Table 2, column 34. Oligo 8A of Sorge is exactly complementary to 7 out of the 8 nucleotides 5'-GAAGAAAA-3' disclosed as nucleotides 733-741 of SEQ ID NO: 1.

Nucleotides 733-741 of SEQ ID NO: 1:	5'-G A A G A A A A-3'
Oligo No. 8A of Sorge:	3'-C A T C T T T-5'

Since Oligo No. 8A is complementary to 7 of 8 nucleotides of nucleotides 733-741 of SEQ ID NO: 1, it would necessarily hybridize to SEQ ID NO: 1 under medium stringency

conditions. Furthermore, since the Oligo No. 8A is complementary to 7 of 8 nucleotides of nucleotides 733-741 of SEQ ID NO: 1, it is also an isolated nucleic acid molecule comprising a nucleotide sequence complementary to a nucleotide sequence encoding the amino acid sequences as set forth in SEQ ID NO:2.

Applicant is reminded that MPEP 2112.01 teaches "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.'"

Response to Arguments

Applicant's arguments filed 11/9/04 have been fully considered but they are addressed below.

With respect to the objection to claim 110, the claim has been amended and the objection is now moot, as such the rejection is withdrawn.

With respect to the rejection of claims under 35 USC 12, 1st paragraph, it is pointed out that the instant claims have been amended such that the claims no recite the limitation "at least 45% similar to SEQ ID NO:2". However a new rejection has been issued with respect to the broad limitations of the instant claims. With respect to the limitations of the instant claims, Applicants argue that the specification has disclosed at least 3 species (e.g., on Page 49 of the specification) that share greater than 98% identity to across the ETS domain and assert that the

"mere identification of the ETS domain of individual polypeptide molecules, a feat that the Examiner concedes to be within the skill of the ordinary artisan, allows those of skill in the art to identify the function of the polypeptide molecule as well as determine whether the various polypeptide molecules share the same functional characteristics" (See page 5 of the response filed 11/9/04).

Claims 160-163 encompass any nucleic acid sequence that encodes a polypeptide having a domain that is at least 98% identical to residues 165-243 of SEQ ID NO: 2. Therefore, the claims now encompass nucleic acids that encode a polypeptide that have a domain that is at least 98% similar to residues 165-243 of SEQ ID NO: 2 but which may have vastly different structure outside of the ETS domain and which may have vastly different functions. For example, the claims encompass polypeptides which may be transcription activators as well as polypeptides which may be transcription inhibitors. The only common structure that exists among all of the species molecules encompassed by the claims is the presence of a domain 98% similar to residues 165-243 of SEQ ID NO:2. It is noted that the limitation "similar" does not mean "identical", therefore the claims encompass nucleic acids encoding proteins having an ETS domain similar to residues 165-243 of SEQ ID NO:2. Although the molecules encompassed by the claims may have a "similar" common structure, there is no indication that all of the molecules encompassed by the claims share the same function. Therefore, the specification has not adequately described the structure-function relationship of the genus of molecules encompassed by the instant claims because the molecules could encode polypeptide that have a domain "98% similar" to residues 165-243 of SEQ ID NO: 2 but have completely different functions.

Claims 164-167 encompass any nucleic acid sequence that encodes a polypeptide having at least 95% similarity to SEQ ID NO: 2. It is respectfully pointed out that the limitation "similar" does not mean "identical", therefore the claims encompass nucleic acids encoding proteins similar to SEQ ID NO:2. Although the molecules encompassed by the claims may have a "similar" common structure, there is no indication that all of the molecules encompassed by the claims share the same function. Therefore, the specification has not adequately described the structure-function relationship of the genus of molecules encompassed by the instant claims because the molecules that encode polypeptides having 95% similar to SEQ ID NO: 2 but which have completely different functions.

Furthermore, with respect to claims 160-167, Applicants argue,

> "The facts set forth above along with the '95% similarity' limitation put these claims squarely within what is considered sufficient written description, as set forth in Example 14 of the Written Description Guidelines, which indicates that disclosure of a single species (Applicants disclose at least three species) with variants having 95% similarity, and disclosure of a function along with an assay that helps the skilled artisan to identify the function (such as that provided in Example 17 of the present specification) is considered sufficient written description under 35 U.S.C. 112, first paragraph." (See p. 5 of the 11/9/04 reply); and,
>
> "As for the claims directed to the 95% variant of SEQ ID N0:2, Applicants respectfully submit that it is well within the skill of those of ordinary skill in the art to identify polypeptide molecules having a sequence 95% similar to that of SEQ ID N0:2, identify its ETS domain (as the Examiner himself acknowledges on page 5 of the Office Action), and determine its function using the directions set forth in the specification in general and specifically in Example 17.

In response, it is respectfully pointed out that the instant claims do not recite any function for the molecules encompassed by the claims. Therefore, the claims encompass molecules that encode polypeptides with indicated "similarity" wherein the polypeptides can have completely different functions. Therefore, the instant claims do no have the same fact pattern as Example 14

of the Guidelines. Furthermore, considering there is no functional limitation set forth in the claims, the assay disclosed would not be sufficient in identification of the function of all the molecules encompassed by the claims. Limiting the claims to the sequence of SEQ ID NO: 1 or an isolated nucleic acid encoding SEQ ID NO: 2 would obviate this rejection.

The applicants also argue,

> "The specification discloses molecules exhibiting SEQ ID NO:1 sequence and those hybridizing under medium stringency conditions to SEQ ID NO:1. Any molecule which hybridizes to SEQ ID NO:1 under medium stringency conditions will exhibit the same functional activity as ELF5. Only nucleic acid molecules closely complementary to SEQ ID NO:1 will bind under these conditions. Accordingly, it would not be necessary to perform any additional experimentation in order to identify the structural elements which are critical to the function of SEQ ID NO:1 related molecules."

In response, the specification has specifically disclosed human ELF5 (SEQ ID NO:1) and mouse ELF5 (SEQ ID NO:3) as well as various primers to these sequences. It is respectfully pointed out that the specification does not appear to disclose other sequences "exhibiting" SEQ ID NO: 1 sequences. Furthermore, with respect to applicants assertion that "Any molecule which hybridizes to SEQ ID NO:1 under medium stringency conditions will exhibit the same functional activity as ELF5", Applicants surely do not intend to assert that any oligonucleotide that hybridizes to SEQ ID NO: 1 under medium stringency conditions will have the same function as ELF5? It is not clear how an oligonucleotide that hybridizes to a sequence would have the same function as the target sequence as target sequences generally encode functional polypeptides while oligonucleotides generally do not encode functional polypeptides. If applicants are intending to assert that an oligonucleotide that hybridizes to SEQ ID NO:1 would identify other sequences that have the same function as SEQ ID NO: 1, it is respectfully pointed out that the oligonucleotide would only identify target molecules that share a common

sequence(s), and the mere presence of a common sequence does not indicate that the molecules have the same function.

With respect to the rejection of claims 110-112, applicants argue that "the claims are now directed to the full-length sequence of SEQ ID NO:2... the Examiner himself has suggested that limiting the claims to full-length sequence would obviate the rejection." (See page 6 of the 11/9/04 reply).

In response it is acknowledged that claim 110 is limited to the full length sequence; however, claim 111 is not. Specifically, claim 111 encompasses a nucleic acid molecule which hybridizes to SEQ ID NO: 1 under medium stringency conditions. Therefore, claim 111 encompass all probes which would hybridize to SEQ ID NO:1 under medium stringency conditions, including oligonucleotide probes. It is noted that deleting the "or which hybridizes to SEQ ID NO: 1 under medium stringency conditions" language from the claim would obviate this rejection.

Allowable Subject Matter

Claims 10 and 113 are allowed.

It is noted that an isolated polynucleotide sequence encoding the amino acid sequence set forth in SEQ ID NO: 2 as well as isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1 is considered allowable subject matter.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell
Art Unit 1635

DAVE TRONG NGUYEN
PRIMARY EXAMINER